

# EXHIBIT A

19230

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Centers for Medicare & Medicaid Services****42 CFR Parts 400, 405, 409, 410, 412, 414, 415, 417, 418, 421, 422, 423, 425, 440, 482, and 510**

[CMS-1744-IFC]

RIN 0938-AU31

**Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency****AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.**ACTION:** Interim final rule with comment period.

**SUMMARY:** This interim final rule with comment period (IFC) gives individuals and entities that provide services to Medicare beneficiaries needed flexibilities to respond effectively to the serious public health threats posed by the spread of the 2019 Novel Coronavirus (COVID-19). Recognizing the urgency of this situation, and understanding that some pre-existing Medicare payment rules may inhibit innovative uses of technology and capacity that might otherwise be effective in the efforts to mitigate the impact of the pandemic on Medicare beneficiaries and the American public, we are changing Medicare payment rules during the Public Health Emergency (PHE) for the COVID-19 pandemic so that physicians and other practitioners, home health and hospice providers, inpatient rehabilitation facilities, rural health clinics (RHCs), and federally qualified health centers (FQHCs) are allowed broad flexibilities to furnish services using remote communications technology to avoid exposure risks to health care providers, patients, and the community. We are also altering the applicable payment policies to provide specimen collection fees for independent laboratories collecting specimens from beneficiaries who are homebound or inpatients (not in a hospital) for COVID-19 testing. We are also expanding, on an interim basis, the list of destinations for which Medicare covers ambulance transports under Medicare Part B. In addition, we are making programmatic changes to the Medicare Diabetes Prevention Program (MDPP) and the Comprehensive Care for Joint Replacement (CJR) Model in light of the PHE, and program-specific requirements for the Quality Payment Program to avoid inadvertently creating

incentives to place cost considerations above patient safety. This IFC will modify the calculation of the 2021 and 2022 Part C and D Star Ratings to address the expected disruption to data collection and measure scores posed by the COVID-19 pandemic and also to avoid inadvertently creating incentives to place cost considerations above patient safety. This rule also amends the Medicaid home health regulations to allow other licensed practitioners to order home health services, for the period of this PHE for the COVID-19 pandemic in accordance with state scope of practice laws. We are also modifying our under arrangements policy during the PHE for the COVID-19 pandemic so that hospitals are allowed broader flexibilities to furnish inpatient services, including routine services outside the hospital.

**DATES:**

**Effective date:** These regulations are effective on March 31, 2020.

**Applicability date:** These regulations are applicable beginning on March 1, 2020.

**Comment date:** To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on June 1, 2020.

**ADDRESSES:** In commenting, please refer to file code CMS-1744-IFC. Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1744-IFC, P.O. Box 8016, Baltimore, MD 21244-8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1744-IFC, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

**FOR FURTHER INFORMATION CONTACT:** Jamie Hermansen, (410) 786-2064, for general information, contact one of the following:

**HAPG\_COVID-19@cms.hhs.gov**, for issues related to telehealth services, and communication technology-based services; frequency limits on subsequent care services in inpatient and non-facility settings, critical care consultations, required "hands-on" visits for ESRD monthly capitation payments; removal of restrictions on technology, and supervision of interactive telecommunications technology; clinical laboratory fee schedule; services furnished by opioid treatment programs; payment under Medicare Part B for teaching physician services and resident moonlighting; remote physiologic monitoring; physician supervision flexibility for outpatient hospital services; payment for office/outpatient evaluation and management visits; counting of resident time at alternate locations; Ambulance Fee Schedule; rural health clinic services; federally qualified health center services; and inpatient hospital services furnished under arrangements outside of the hospital. (Note this email address has an underscore "\_" between "HAPG" and "COVID-19".)

**IRFCoverage@cms.hhs.gov**, for issues related to the Medicare inpatient rehabilitation facility benefits.

**NCDsPublicHealthEmergency@cms.hhs.gov**, for issues related to national coverage determination and local coverage determination requirements.

**PartCandDStarRatings@cms.hhs.gov**, for issues related to Medicare Parts C and D quality rating system.

**MedicaidHomeHealthRule@cms.hhs.gov**, for issues related to Medicaid home health provider flexibility.

Hillary Loeffler, (410) 786-0456, **HomeHealthPolicy@cms.hhs.gov**, or **HospicePolicy@cms.hhs.gov**, for issues related to the Medicare home health and hospice benefits.

Megan Hyde, (410) 786-3247, and Rebecca Cole, (410) 786-1589, for issues related to Innovation Center Models, and alternative payment model treatment under the Quality Payment Program.

Kim Spalding Bush, (410) 786-3232, and Fiona Larbi, (410) 786-7224, for issues related to the Medicare Shared Savings Program.

Molly MacHarris, (410) 786-4461, for issues related to the Merit-based Incentive Payment System (MIPS).

Heather Holsey, (410) 786-0028, for Comprehensive Care for Joint Replacement model.

Amanda Rhee, (410) 786-3888, and Elizabeth Matthews, (410) 786-5433, for Medicare Diabetes Prevention Program expanded model.

Brittany LaCouture, (410) 786–0481, for Alternative Payment Model provisions of the Quality Payment Program.

CAPT Scott Cooper, USPHS, (410) 786–9496, for issues related to special requirements for psychiatric hospitals.

**SUPPLEMENTARY INFORMATION:**

*Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://regulations.gov>. Follow the search instructions on that website to view public comments.

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## Addenda Available Only Through the Internet on the CMS Website

The Addenda along with other supporting documents and tables referenced in this interim final rule with comment period (IFC) are available through the internet on the CMS website at <https://www.cms.gov/>. For this IFC, refer to item CMS–1744–IFC. Readers who experience any problems accessing any of the Addenda or other documents referenced in this IFC and posted on the CMS website identified above should contact [HAPG\\_COVID-19@cms.hhs.gov](mailto:HAPG_COVID-19@cms.hhs.gov).

## CPT (Current Procedural Terminology) Copyright Notice

Throughout this IFC, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 2019 American Medical Association. All Rights Reserved. CPT is a registered

trademark of the American Medical Association (AMA). Applicable Federal Acquisition Regulations (FAR) and Defense Federal Acquisition Regulations (DFAR) apply.

## I. Background

The United States is responding to an outbreak of respiratory disease caused by a novel (new) coronavirus that was first detected in China and which has now been detected in more than 190 locations internationally, including in all 50 States and the District of Columbia. The virus has been named “SARS-CoV–2” and the disease it causes has been named “coronavirus disease 2019” (abbreviated “COVID–19”).

On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization (WHO) declared the outbreak a “Public Health Emergency of international concern” (PHEIC). On January 31, 2020, Health and Human Services Secretary, Alex M. Azar II, declared a PHE for the United States to aid the nation’s healthcare community in responding to COVID–19 (hereafter referred to as the PHE for the COVID–19 pandemic). On March 11, 2020, the WHO publicly characterized COVID–19 as a pandemic. On March 13, 2020 the President of the United States declared the COVID–19 outbreak a national emergency.

Coronaviruses are a large family of viruses that are common in people and many different species of animals, including camels, cattle, cats, and bats. Rarely, animal coronaviruses can infect people and then spread between people such as with MERS-CoV, SARS-CoV, and now with this new virus (COVID–19).

The complete clinical picture with regard to COVID–19 is not fully known. Reported illnesses have ranged from very mild (including some with no reported symptoms) to severe, including illness resulting in death. While information so far suggests that most COVID–19 illness is mild, a report out of China suggests serious illness occurs in 16 percent of cases. Older people and people of all ages with severe chronic medical conditions—like heart disease, lung disease and diabetes, for example—seem to be at higher risk of developing serious COVID–19 illness.<sup>1</sup>

A pandemic is a global outbreak of disease. Pandemics happen when a new virus emerges to infect people and can spread between people sustainably. Because there is little to no pre-existing

<sup>1</sup> <https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/summary.html>.

immunity against the new virus, it spreads worldwide. The virus that causes COVID–19 is infecting people and spreading easily from person-to-person. This is the first pandemic known to be caused by the emergence of a new coronavirus.<sup>2</sup>

People in places where ongoing community spread of the virus that causes COVID–19 has been reported are at elevated risk of exposure, with the level of risk dependent on the location. Healthcare workers caring for patients with COVID–19 are at elevated risk of exposure. Close contacts of persons with COVID–19 also are at elevated risk of exposure.

Early information out of China, where COVID–19 first started, shows that some people are at higher risk of getting very sick from this illness. This includes:

- Older adults, with risk increasing by age.
- People who have serious chronic medical conditions like:
  - ++ Heart disease.
  - ++ Diabetes.
  - ++ Lung disease.

The Centers for Disease Control and Prevention (CDC) has developed guidance to help in the risk assessment and management of people with potential exposures to COVID–19, including recommending that health care professionals make every effort to interview a person under investigation for infection by telephone, text monitoring system, or video conference.<sup>3</sup>

As the healthcare community works to implement and establish recommended infection prevention and control practices, regulatory agencies under appropriate waiver authority granted by the PHE for the COVID–19 pandemic declaration are also working to revise and implement regulations that work in concert with healthcare community infection prevention and treatment practices. Based on the current and projected increase in rate of incidence of the COVID–19 disease in the US population, and observed fatalities in the elderly population, who are particularly vulnerable due to age and co-morbidities, and additionally, impact on health workers that are at increased risk due to treating the population, we believe that certain Medicare and Medicaid regulations that may offer providers flexibilities in furnishing services to combat the COVID–19 pandemic should be reviewed and revised as appropriate.

We are addressing some of these regulations in this interim final rule with comment period (IFC) to ensure that sufficient health care items and services are available to meet the needs of individuals enrolled in the programs under Title XVIII (Medicare) and Title XIX (Medicaid) of the Social Security Act (the Act).

In this extraordinary circumstance, we recognize that public exposure greatly increases the overall risk to public health. We believe that this increased risk produces an immediate change, not only in the circumstances under which services can safely occur, but also results in an immediate change to the business relationships between providers, suppliers, and practitioners. By increasing access to services delivered using telecommunications technology, increasing access to testing in a patient's home, and improving infection control, this IFC will provide the necessary flexibility for Medicare beneficiaries to be able to receive medically necessary services without jeopardizing their health or the health of those who are providing those services, while minimizing the overall risk to public health.

## II. Provisions of the Interim Final Rule

In this IFC, we are defining the term, "Public Health Emergency," in the regulation at 42 CFR 400.200, which contains definitions that apply under the entirety of chapter 400 of title 42 of the CFR. The definition identifies the PHE determined to exist nationwide by the Secretary of Health and Human services under section 319 of the Public Health Service Act on January 31, 2020, as a result of confirmed cases of COVID–19, including any subsequent renewals.

### A. Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

Section 1834(m) of the Act specifies the payment amounts and circumstances under which Medicare makes payment for a discrete set of services, all of which must ordinarily be furnished in-person, when they are instead furnished using interactive, real-time telecommunication technology. When furnished under the telehealth rules, many of these specified Medicare telehealth services are still reported using codes that describe "face-to-face" services but are furnished using audio/video, real-time communication technology instead of in-person. The list of these eligible telehealth services is published on the CMS website at <https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html>.

In contrast, Medicare pays separately for other professional services that are commonly furnished remotely using telecommunications technology, but that do not usually require the patient to be present in-person with the practitioner when they are furnished. These services, including remote physician interpretation of diagnostic tests, care management services and virtual check-ins among many others, are considered physicians' services in the same way as services that are furnished in-person without the use of telecommunications technology. They are covered and paid in the same way as services delivered without the use of telecommunications technology, but are not considered Medicare telehealth services and are not subject to the conditions of payment under section 1834(m) of the Act.

On March 17, 2020, we announced the expansion of telehealth services on a temporary and emergency basis pursuant to waiver authority added under section 1135(b)(8) of the Act by the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (Pub. L. 116–123, March 6, 2020). Starting on March 6, 2020, Medicare can pay for telehealth services, including office, hospital, and other visits furnished by physicians and other practitioners to patients located anywhere in the country, including in a patient's place of residence. In the context of the PHE for the COVID–19 pandemic, we recognize that physicians and other health care professionals are faced with new challenges regarding potential exposure risks, for people with Medicare, for health care providers, and for members of the community at large. For example, the CDC has urged health care professionals to make every effort to interview persons under investigation for infection by telephone, text messaging system, or video conference instead of in-person. To facilitate the use of telecommunications technology as a safe substitute for in-person services, we are, on an interim basis, adding many services to the list of eligible Medicare telehealth services, eliminating frequency limitations and other requirements associated with particular services furnished via telehealth, and clarifying several payment rules that apply to other services that are furnished using telecommunications technologies that can reduce exposure risks.

As discussed in this IFC and in prior rulemaking, several conditions must be met for Medicare to make payment for telehealth services under the Physician Fee Schedule (PFS). For further details, see the full discussion of the scope of

<sup>2</sup> <https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/summary.html>.

<sup>3</sup> <https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/summary.html>.

Medicare telehealth services in the “Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program” final rule (82 FR 53006, November 17, 2017) (hereinafter referred to as the CY 2018 PFS final rule) and in our regulations at 42 CFR 410.78 and 414.65.

#### 1. Site of Service Differential for Medicare Telehealth Services

Under the PFS, there are two payment rates for many physicians’ services: The facility rate; and the non-facility, or office, rate. The PFS non-facility rate is the single amount paid to a physician or other practitioner for services furnished in their office. The PFS facility rate is the amount generally paid to a professional when a service is furnished in a setting of care, like a hospital, where Medicare is making a separate payment to an entity in addition to the payment to the billing physician or practitioner. This separate payment, often referred to as a “facility fee” reflects the facility’s costs associated with the service (clinical staff, supplies and equipment) and is paid in addition to what is paid to the professional through the PFS.

We note that, in accordance with section 1834(m)(2)(B) of the Act, a facility fee is, in most cases, paid to the “originating site” where the beneficiary is located at the time a telehealth service is furnished. The payment amount for the telehealth originating site facility fee is a nationally applicable flat fee, paid without geographic or site of service adjustments that generally apply to payments for different kinds of services furnished by Medicare providers and suppliers.

For Medicare telehealth services, we currently make payment to the billing physician or practitioner at the PFS facility rate since the facility costs (clinical staff, supplies, and equipment) associated with furnishing the service would generally be incurred by the originating site, where the patient is located, and not by the practitioner at the distant site; and because the statute requires Medicare to pay an originating site facility fee to the site that hosts the patient.

When a physician or practitioner submits a claim for their services, including claims for telehealth services, they include a place of service (POS) code that is used to determine whether a service is paid using the facility or non-facility rate. Currently, CMS requires that claims for Medicare

telehealth services include the POS code 02, which is specific to telehealth services.

Under the waiver authority exercised by the Secretary in response to the PHE for the COVID–19 pandemic, Medicare telehealth services can be furnished to patients wherever they are located, including in the patient’s home. As provided by the amendments to section 1135(b)(8) of the Act, when telehealth services are furnished under the waiver to beneficiaries located in places that are not identified as permissible originating sites in section 1834(m)(4)(C)(ii)(I) through (IX) of the Act, no originating site facility fee is paid. We also recognize that as physician practices suddenly transition a potentially significant portion of their services from in-person to telehealth visits in the context of the PHE for the COVID–19 pandemic, the relative resource costs of furnishing these services via telehealth may not significantly differ from the resource costs involved when these services are furnished in person. For example, we expect that physician offices will continue to employ nursing staff to engage with patients during telehealth visits or to coordinate pre- or post-visit care, regardless of whether or not the visit takes place in person, as it would have outside of the PHE for the COVID–19 pandemic, or through telehealth in the context of the PHE for the COVID–19 pandemic. Consequently, the assumptions that have supported payment of telehealth services at the PFS facility rate would not apply in many circumstances for services furnished during the PHE for the COVID–19 pandemic. Instead, we believe that, as more telehealth services are furnished to patients wherever they are located rather than in statutory originating sites, it would be appropriate to assume that the relative resource costs of services furnished through telehealth should be reflected in the payment to the furnishing physician or practitioner as if they furnished the services in person, and to assign the payment rate that ordinarily would have been paid under the PFS were the services furnished in-person. For example, a physician practicing in an office setting who, under the PHE for the COVID–19 pandemic, sees patients via telehealth instead of in person would be paid at the non-facility, or office, rate for these services. Similarly, a physician who typically sees patients in an outpatient provider-based clinic of a hospital would be paid the facility rate for services newly furnished via telehealth.

To implement this change on an interim basis, we are instructing physicians and practitioners who bill for Medicare telehealth services to report the POS code that would have been reported had the service been furnished in person. This will allow our systems to make appropriate payment for services furnished via Medicare telehealth which, if not for the PHE for the COVID–19 pandemic, would have been furnished in person, at the same rate they would have been paid if the services were furnished in person. Given the potential importance of using telehealth services as means of minimizing exposure risks for patients, practitioners, and the community at large, we believe this interim change will maintain overall relativity under the PFS for similar services and eliminate potential financial deterrents to the clinically appropriate use of telehealth. Because we currently use the POS code on the claim to identify Medicare telehealth services, we are finalizing on an interim basis the use of the CPT telehealth modifier, modifier 95, which should be applied to claim lines that describe services furnished via telehealth. We note that we are maintaining the facility payment rate for services billed using the general telehealth POS code 02, should practitioners choose, for whatever reason, to maintain their current billing practices for Medicare telehealth during the PHE for the COVID–19 pandemic.

#### 2. Adding Services to the List of Medicare Telehealth Services

In the “Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2003 and Inclusion of Registered Nurses in the Personnel Provision of the Critical Access Hospital Emergency Services Requirement for Frontier Areas and Remote Locations” final rule with comment period (67 FR 79988, December 31, 2002) (hereinafter referred to as the CY 2003 PFS final rule with comment period), we established a process for adding services to or deleting services from the list of Medicare telehealth services in accordance with section 1834(m)(4)(F)(ii) of the Act. This process provides the public with an ongoing opportunity to submit requests for adding services, which we then review. We have also routinely reviewed potential services for addition to the list of telehealth services and sought comment on any such proposed additions. Under this process, we assign any potential addition to the list of telehealth services to one of the following two categories:

- *Category 1:* Services that are similar to professional consultations, office visits, and office psychiatry services that are currently on the list of telehealth services. In reviewing these requests, we look for similarities between the requested and existing telehealth services for the roles of, and interactions among, the beneficiary, the physician (or other practitioner) at the distant site and, if necessary, the telepresenter, a practitioner who is present with the beneficiary in the originating site. We also look for similarities in the telecommunications system used to deliver the service; for example, the use of interactive audio and video equipment.

- *Category 2:* Services that are not similar to those on the current list of telehealth services. Our review of these requests includes an assessment of whether the service is accurately described by the corresponding code when furnished via telehealth and whether the use of a telecommunications system to furnish the service produces demonstrated clinical benefit to the patient. Submitted evidence should include both a description of relevant clinical studies that demonstrate the service furnished by telehealth to a Medicare beneficiary improves the diagnosis or treatment of an illness or injury or improves the functioning of a malformed body part, including dates and findings, and a list and copies of published peer reviewed articles relevant to the service when furnished via telehealth. Our evidentiary standard of clinical benefit does not include minor or incidental benefits.

Some examples of clinical benefit include the following:

- Ability to diagnose a medical condition in a patient population without access to clinically appropriate in-person diagnostic services.
- Treatment option for a patient population without access to clinically appropriate in-person treatment options.
- Reduced rate of complications.
- Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process).
- Decreased number of future hospitalizations or physician visits.
- More rapid beneficial resolution of the disease process treatment.
- Decreased pain, bleeding, or other quantifiable symptom.
- Reduced recovery time.

The list of telehealth services, including the additions described later in this section, can be located on the CMS website at <https://www.cms.gov/>

#### *Medicare/Medicare-General-Information/Telehealth/index.html.*

On an interim basis, we are adding the following services to the Medicare telehealth list on a Category 2 basis for the duration of this PHE for the COVID-19 pandemic, for telehealth services with dates of service beginning March 1, 2020 through the end of the declared PHE including any subsequent renewals. When we previously considered adding these services to the list of telehealth services, either through a public request or through our own internal review, we considered whether or not these services met the category 1 or category 2 criteria. In many cases we reviewed requests to add these services on a category 1 basis but did not receive or identify information that allowed us to review the services on a category 2 basis. While we do not believe the context of this PHE for the COVID-19 pandemic changes the assessment of these services as category 1, we have reassessed all of these services on a category 2 basis in the context of the widespread presence of COVID-19 in the community. Given the exposure risks for beneficiaries, the health care work force, and the community at large, in-person interaction between professionals and patients poses an immediate potential risk that would not have been present when we previously reviewed these services. This new risk creates a unique circumstance where health care professionals need to weigh the risks associated with disease exposure so they can bill Medicare for the service. For example, certain persons, especially older adults who are particularly vulnerable to this specific virus, those considered at risk because of underlying health conditions, and those known to be recently exposed or diagnosed, and therefore, likely to spread the virus to others, are often being directed by local public health officials to self-isolate as much as possible. At the same time, we note that the risks to medical professionals treating patients is high and we consider it likely that medical professionals will try to treat patients as effectively as possible without exposing themselves or their patients unnecessarily. In some cases, use of telecommunication technology could mitigate the exposure risk, and in such cases, there is a clear clinical benefit of using such technology in furnishing the service. In other words, patients who should not be seen by a professional in-person due to the exposure risk are highly likely to be without access to clinically appropriate treatment or diagnostic options unless they have access to services furnished

through interactive communication technology. Therefore, in the context of the PHE for the COVID-19 pandemic, we believe all of the following services meet the category 2 criteria to be added to the list of telehealth services on the basis that there is a patient population that would otherwise not have access to clinically appropriate treatment. We note that, as with other services on the Medicare telehealth list, it may not be clinically appropriate or possible to use telecommunications technology to furnish these particular services to every person or in every circumstance. However, in the context of the PHE for the COVID-19 pandemic with specific regard to the exposure risks noted above, we recognize the clinical benefit of access to medically reasonable and necessary services furnished using telecommunications technology as opposed to the potential lack of access that could occur to mitigate the risk of disease exposure. In light of the PHE for the COVID-19 pandemic, the demand for physicians in areas heavily impacted by COVID-19 or under served by clinicians may intensify, resulting in a need for critical care services for patients with suspected or diagnosed COVID-19 and those who are in acute care settings due to other conditions. These practitioners may be working with nurses, consulting with other healthcare professionals, writing orders, looking at images, communicating with family members for patients with a number of acute conditions. The CPT codes describing E/M services reflect an assumption that the nature of the work involved in evaluation and management visits varies, in part, based on the setting of care and the patient's status. Consequently, there are separate sets of E/M codes for different settings of care, such as office/outpatient codes, nursing facility codes, or emergency department codes. We expect physicians and other practitioners to use the E/M code that best describes the nature of the care they are providing, regardless of the physical location or status of the patient. Under ordinary circumstances, we would expect the kind of E/M code reported to generally align with the physical location or status of the patient. In the context of the PHE, we recognize that the relationship among the setting of care, patient status, and kind of E/M code reported may depend on the needs of local communities and the capacity of local health care institutions. Consequently, we are reiterating that practitioners should report the E/M code that best describes the nature of the care they are providing.

We are adding the following codes to the existing list of telehealth services on a Category 2 basis for the PHE for the COVID-19 pandemic:

3. Emergency Department Visits: CPT Codes

- 99281 (Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: A problem focused history; A problem focused examination; and Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self limited or minor.)

• 99282 (Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; and Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity.)

• 99283 (Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate severity.)

• 99284 (Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: A detailed history; A detailed examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of high severity, and require urgent evaluation by the physician, or other qualified health care professionals but do not pose an

immediate significant threat to life or physiologic function.)

- 99285 (Emergency department visit for the evaluation and management of a patient, which requires these 3 key components within the constraints imposed by the urgency of the patient's clinical condition and/or mental status: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of high severity and pose an immediate significant threat to life or physiologic function.)

4. Initial and Subsequent Observation, and Observation Discharge Day Management: CPT Codes

- 99217 (Observation care discharge day management (This code is to be utilized to report all services provided to a patient on discharge from outpatient hospital "observation status" if the discharge is on other than the initial date of "observation status." To report services to a patient designated as "observation status" or "inpatient status" and discharged on the same date, use the codes for Observation or Inpatient Care Services [including Admission and Discharge Services, 99234–99236 as appropriate.]

• 99218 (Initial observation care, per day, for the evaluation and management of a patient which requires these 3 key components: A detailed or comprehensive history; A detailed or comprehensive examination; and Medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission to outpatient hospital "observation status" are of low severity. Typically, 30 minutes are spent at the bedside and on the patient's hospital floor or unit.)

• 99219 (Initial observation care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the

problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission to outpatient hospital "observation status" are of moderate severity. Typically, 50 minutes are spent at the bedside and on the patient's hospital floor or unit.)

- 99220 (Initial observation care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission to outpatient hospital "observation status" are of high severity. Typically, 70 minutes are spent at the bedside and on the patient's hospital floor or unit.)

• 99224 (Subsequent observation care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: Problem focused interval history; Problem focused examination; Medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is stable, recovering, or improving. Typically, 15 minutes are spent at the bedside and on the patient's hospital floor or unit.)

• 99225 (Subsequent observation care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: An expanded problem focused interval history; An expanded problem focused examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is responding inadequately to therapy or has developed a minor complication. Typically, 25 minutes are spent at the bedside and on the patient's hospital floor or unit.)

- 99226 (Subsequent observation care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: A detailed interval history; A detailed examination; Medical

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*decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is unstable or has developed a significant complication or a significant new problem. Typically, 35 minutes are spent at the bedside and on the patient's hospital floor or unit.)*

- 99234 (*Observation or inpatient hospital care, for the evaluation and management of a patient including admission and discharge on the same date, which requires these 3 key components: A detailed or comprehensive history; A detailed or comprehensive examination; and Medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually the presenting problem(s) requiring admission are of low severity. Typically, 40 minutes are spent at the bedside and on the patient's hospital floor or unit.)*

- 99235 (*Observation or inpatient hospital care, for the evaluation and management of a patient including admission and discharge on the same date, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually the presenting problem(s) requiring admission are of moderate severity. Typically, 50 minutes are spent at the bedside and on the patient's hospital floor or unit.)*

- 99236 (*Observation or inpatient hospital care, for the evaluation and management of a patient including admission and discharge on the same date, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually the presenting problem(s) requiring admission are of high severity. Typically, 55 minutes are*

*spent at the bedside and on the patient's hospital floor or unit.)*

#### 5. Initial Hospital Care and Hospital Discharge Day Management: CPT Codes

- 99221 (*Initial hospital care, per day, for the evaluation and management of a patient, which requires these 3 key components: A detailed or comprehensive history; A detailed or comprehensive examination; and Medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of low severity. Typically, 30 minutes are spent at the bedside and on the patient's hospital floor or unit.)*

- 99222 (*Initial hospital care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of moderate severity. Typically, 35 minutes are spent at the bedside and on the patient's hospital floor or unit.)*

- 99223 (*Initial hospital care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of high severity. Typically, 45 minutes are spent at the bedside and on the patient's facility floor or unit.)*

- 99238 (*Hospital discharge day management; 30 minutes or less)*
- 99239 (*Hospital discharge day management; more than 30 minutes*)

#### 6. Initial Nursing Facility Visits and Nursing Facility Discharge Day Management: CPT Codes

- 99204 (*Initial nursing facility care, per day, for the evaluation and management of a patient, which requires these 3 key components: A*

*detailed or comprehensive history; A detailed or comprehensive examination; and Medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of low severity. Typically, 25 minutes are spent at the bedside and on the patient's facility floor or unit.)*

- 99305 (*Initial nursing facility care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of moderate severity. Typically, 30 minutes are spent at the bedside and on the patient's facility floor or unit.)*

- 99306 (*Initial nursing facility care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of high severity. Typically, 45 minutes are spent at the bedside and on the patient's facility floor or unit.)*

- 99315 (*Nursing facility discharge day management; 30 minutes or less*)

- 99316 (*Nursing facility discharge day management; more than 30 minutes*)

#### 7. Critical Care Services: CPT Codes

- 99291 (*Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes*)

- 99292 (*Critical care, evaluation and management of the critically ill or critically injured patient; each additional 30 minutes (List separately in addition to code for primary service)*)

8. Domiciliary, Rest Home, or Custodial Care Services: CPT Codes

- 99327 (Domiciliary or rest home visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of high severity. Typically, 60 minutes are spent with the patient and/or family or caregiver.)

- 99328 (Domiciliary or rest home visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is unstable or has developed a significant new problem requiring immediate physician attention. Typically, 75 minutes are spent with the patient and/or family or caregiver.)

- 99334 (Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A problem focused interval history; A problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self-limited or minor. Typically, 15 minutes are spent with the patient and/or family or caregiver.)

- 99335 (Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: An expanded problem focused interval history; An expanded problem focused examination; Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate

severity. Typically, 25 minutes are spent with the patient and/or family or caregiver.)

- 99336 (Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A detailed interval history; A detailed examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 40 minutes are spent with the patient and/or family or caregiver.)

- 99337 (Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A comprehensive interval history; A comprehensive examination; Medical decision making of moderate to high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. The patient may be unstable or may have developed a significant new problem requiring immediate physician attention. Typically, 60 minutes are spent with the patient and/or family or caregiver.)

#### 9. Home Visits: CPT Codes

- 99341 (Home visit for the evaluation and management of a new patient, which requires these 3 key components: A problem focused history; A problem focused examination; and Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low severity. Typically, 20 minutes are spent face-to-face with the patient and/or family.)

- 99342 (Home visit for the evaluation and management of a new patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; and Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies

are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate severity. Typically, 30 minutes are spent face-to-face with the patient and/or family.)

- 99343 (Home visit for the evaluation and management of a new patient, which requires these 3 key components: A detailed history; A detailed examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 45 minutes are spent face-to-face with the patient and/or family.)

- 99344 (Home visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of high severity. Typically, 60 minutes are spent face-to-face with the patient and/or family.)

- 99345 (Home visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is unstable or has developed a significant new problem requiring immediate physician attention. Typically, 75 minutes are spent face-to-face with the patient and/or family.)

- 99347 (Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A problem focused interval history; A problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided

consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self limited or minor. Typically, 15 minutes are spent face-to-face with the patient and/or family.)

- 99348 (Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: An expanded problem focused interval history; An expanded problem focused examination; Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity. Typically, 25 minutes are spent face-to-face with the patient and/or family.)

- 99349 (Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A detailed interval history; A detailed examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are moderate to high severity. Typically, 40 minutes are spent face-to-face with the patient and/or family.)

- 99350 (Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A comprehensive interval history; A comprehensive examination; Medical decision making of moderate to high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. The patient may be unstable or may have developed a significant new problem requiring immediate physician attention. Typically, 60 minutes are spent face-to-face with the patient and/or family.)

#### 10. Inpatient Neonatal and Pediatric Critical Care: CPT Codes

- 99468 (Initial inpatient neonatal critical care, per day, for the evaluation and management of a critically ill neonate, 28 days of age or younger)

- 99469 (Subsequent inpatient neonatal critical care, per day, for the evaluation and management of a critically ill neonate, 28 days of age or younger)

- 99471 (Initial inpatient pediatric critical care, per day, for the evaluation and management of a critically ill infant or young child, 29 days through 24 months of age)

- 99472 (Subsequent inpatient pediatric critical care, per day, for the evaluation and management of a critically ill infant or young child, 29 days through 24 months of age)

- 99473 (Self-measured blood pressure using a device validated for clinical accuracy; patient education/training and device calibration)

- 99475 (Initial inpatient pediatric critical care, per day, for the evaluation and management of a critically ill infant or young child, 2 through 5 years of age)

- 99476 (Subsequent inpatient pediatric critical care, per day, for the evaluation and management of a critically ill infant or young child, 2 through 5 years of age)

#### 11. Initial and Continuing Intensive Care Services: CPT Codes

- 99477 (Initial hospital care, per day, for the evaluation and management of the neonate, 28 days of age or younger, who requires intensive observation, frequent interventions, and other intensive care services)

- 99478 (Subsequent intensive care, per day, for the evaluation and management of the recovering very low birth weight infant (present body weight less than 1500 grams))

- 99479 (Subsequent intensive care, per day, for the evaluation and management of the recovering low birth weight infant (present body weight of 1500–2500 grams))

- 99480 (Subsequent intensive care, per day, for the evaluation and management of the recovering infant (present body weight of 2501–5000 grams))

#### 12. Care Planning for Patients With Cognitive Impairment: CPT Code

- 99483 (Assessment of and care planning for a patient with cognitive impairment, requiring an independent historian, in the office or other outpatient, home or domiciliary or rest home, with all of the following required elements: Cognition-focused evaluation including a pertinent history and examination; Medical decision making of moderate or high complexity; Functional assessment (eg, basic and instrumental activities of daily living), including decision-making capacity; Use of standardized instruments for

- staging of dementia (eg, functional assessment staging test [FAST], clinical dementia rating [CDR]; Medication reconciliation and review for high-risk medications; Evaluation for neuropsychiatric and behavioral symptoms, including depression, including use of standardized screening instrument(s); Evaluation of safety (eg, home), including motor vehicle operation; Identification of caregiver(s), caregiver knowledge, caregiver needs, social supports, and the willingness of caregiver to take on caregiving tasks; Development, updating or revision, or review of an Advance Care Plan; Creation of a written care plan, including initial plans to address any neuropsychiatric symptoms, neurocognitive symptoms, functional limitations, and referral to community resources as needed (eg, rehabilitation services, adult day programs, support groups) shared with the patient and/or caregiver with initial education and support. Typically, 50 minutes are spent face-to-face with the patient and/or family or caregiver.)

#### 13. Group Psychotherapy: CPT Code

- 90853 (Group psychotherapy (other than of a multiple-family group))

#### 14. End-Stage Renal Disease (ESRD) Services: CPT Codes

- 90952 (End-stage renal disease (ESRD) related services monthly, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 2–3 face-to-face visits by a physician or other qualified health care professional per month)

- 90953 (End-stage renal disease (ESRD) related services monthly, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 1 face-to-face visit by a physician or other qualified health care professional per month)

- 90959 (End-stage renal disease (ESRD) related services monthly, for patients 12–19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 1 face-to-face visit by a physician or other qualified health care professional per month)

- 90962 (End-stage renal disease (ESRD) related services monthly, for patients 20 years of age and older; with 1 face-to-face visit by a physician or other qualified health care professional per month)

**15. Psychological and Neuropsychological Testing: CPT Codes**

- 96130 (*Psychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour*)

- 96131 (*Psychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; each additional hour (List separately in addition to code for primary procedure)*)

- 96132 (*Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour*)

- 96133 (*Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; each additional hour (List separately in addition to code for primary procedure)*)

- 96136 (*Psychological or neuropsychological test administration and scoring by physician or other qualified health care professional, two or more tests, any method; first 30 minutes*)

- 96137 (*Psychological or neuropsychological test administration and scoring by physician or other qualified health care professional, two or more tests, any method; each additional 30 minutes (List separately in addition to code for primary procedure)*)

- 96138 (*Psychological or neuropsychological test administration and scoring by technician, two or more tests, any method; first 30 minutes*)

- 96139 (*Psychological or neuropsychological test administration and scoring by technician, two or more tests, any method; each additional 30 minutes (List separately in addition to code for primary procedure)*)

**16. Therapy Services**

We have received a number of requests, most recently for CY 2018 PFS rulemaking, that we add therapy services to the Medicare telehealth list. In the CY 2018 PFS final rule, we noted that section 1834(m)(4)(E) of the Act specifies the types of practitioners who may furnish and bill for Medicare telehealth services as those practitioners under section 1842(b)(18)(C) of the Act. Physical therapists, occupational therapists and speech-language pathologists are not among the practitioners identified in section 1842(b)(18)(C) of the Act. We stated in the Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Bid Pricing Data Release; Medicare Advantage and Part D Medical Loss Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model; Medicare Shared Savings Program Requirements' final rule (81 FR 80198, November 15, 2016) (hereinafter referred to as the CY 2017 PFS final rule) that because these services are predominantly furnished by physical therapists, occupational therapists and speech-language pathologists, we did not believe it would be appropriate to add them to the list of telehealth services at this time. In a subsequent request to consider adding these services for 2018, the original requester suggested that we might propose these services to be added to the list so that they can be furnished via telehealth when furnished by eligible distant site practitioners. Since the majority of the codes are furnished over 90 percent of the time by therapy professionals, who are not included on the statutory list of eligible distant site practitioners, we stated that we believed that adding therapy services to the telehealth list could result in confusion about who is authorized to furnish and bill for these services when furnished via telehealth.

In light of the PHE for the COVID-19 pandemic, we believe that the risks associated with confusion are outweighed by the potential benefits for circumstances when these services might be furnished via telehealth by eligible distant site practitioners. We believe this is sufficient clinical evidence to support the addition of therapy services to the Medicare telehealth list on a category 2 basis. However, we note that the statutory definition of distant site practitioners under section 1834(m) of the Act does not include physical therapists,

occupational therapists, or speech-language pathologists, meaning that it does not provide for payment for these services as Medicare telehealth services when furnished by physical therapists, occupational therapists, or speech-language pathologists.

**CPT codes:**

- 97161 (*Physical therapy evaluation: low complexity, requiring these components: A history with no personal factors and/or comorbidities that impact the plan of care; An examination of body system(s) using standardized tests and measures addressing 1–2 elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; A clinical presentation with stable and/or uncomplicated characteristics; and Clinical decision making of low complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 20 minutes are spent face-to-face with the patient and/or family.)*

- 97162 (*Physical therapy evaluation: moderate complexity, requiring these components: A history of present problem with 1–2 personal factors and/or comorbidities that impact the plan of care; An examination of body systems using standardized tests and measures in addressing a total of 3 or more elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; An evolving clinical presentation with changing characteristics; and Clinical decision making of moderate complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 30 minutes are spent face-to-face with the patient and/or family.)*

- 97163 (*Physical therapy evaluation: high complexity, requiring these components: A history of present problem with 3 or more personal factors and/or comorbidities that impact the plan of care; An examination of body systems using standardized tests and measures addressing a total of 4 or more elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; A clinical presentation with unstable and unpredictable characteristics; and Clinical decision making of high complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 45 minutes are spent face-to-face with the patient and/or family.)*
- 97164 (*Re-evaluation of physical therapy established plan of care,*

requiring these components: An examination including a review of history and use of standardized tests and measures is required; and Revised plan of care using a standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 20 minutes are spent face-to-face with the patient and/or family.)

- 97165 (Occupational therapy evaluation, low complexity, requiring these components: An occupational profile and medical and therapy history, which includes a brief history including review of medical and/or therapy records relating to the presenting problem; An assessment(s) that identifies 1–3 performance deficits (ie, relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and Clinical decision making of low complexity, which includes an analysis of the occupational profile, analysis of data from problem-focused assessment(s), and consideration of a limited number of treatment options. Patient presents with no comorbidities that affect occupational performance. Modification of tasks or assistance (eg, physical or verbal) with assessment(s) is not necessary to enable completion of evaluation component. Typically, 30 minutes are spent face-to-face with the patient and/or family.)

- 97166 (Occupational therapy evaluation, moderate complexity, requiring these components: An occupational profile and medical and therapy history, which includes an expanded review of medical and/or therapy records and additional review of physical, cognitive, or psychosocial history related to current functional performance; An assessment(s) that identifies 3–5 performance deficits (ie, relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and Clinical decision making of moderate analytic complexity, which includes an analysis of the occupational profile, analysis of data from detailed assessment(s), and consideration of several treatment options. Patient may present with comorbidities that affect occupational performance. Minimal to moderate modification of tasks or assistance (eg, physical or verbal) with assessment(s) is necessary to enable patient to complete evaluation component. Typically, 45 minutes are spent face-to-face with the patient and/or family.)

- 97167 (Occupational therapy evaluation, high complexity, requiring these components: An occupational

profile and medical and therapy history, which includes review of medical and/or therapy records and extensive additional review of physical, cognitive, or psychosocial history related to current functional performance; An assessment(s) that identifies 5 or more performance deficits (ie, relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and Clinical decision making of high analytic complexity, which includes an analysis of the patient profile, analysis of data from comprehensive assessment(s), and consideration of multiple treatment options. Patient presents with comorbidities that affect occupational performance. Significant modification of tasks or assistance (eg, physical or verbal) with assessment(s) is necessary to enable patient to complete evaluation component. Typically, 60 minutes are spent face-to-face with the patient and/or family.)

- 97168 (Re-evaluation of occupational therapy established plan of care, requiring these components: An assessment of changes in patient functional or medical status with revised plan of care; An update to the initial occupational profile to reflect changes in condition or environment that affect future interventions and/or goals; and A revised plan of care. A formal reevaluation is performed when there is a documented change in functional status or a significant change to the plan of care is required. Typically, 30 minutes are spent face-to-face with the patient and/or family.)

- 97110 (Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility)

- 97112 (Therapeutic procedure, 1 or more areas, each 15 minutes; neuromuscular reeducation of movement, balance, coordination, kinesthetic sense, posture, and/or proprioception for sitting and/or standing activities)

- 97116 (Therapeutic procedure, 1 or more areas, each 15 minutes; gait training (includes stair climbing)

- 97535 (Self-care/home management training (eg, activities of daily living (ADL) and compensatory training, meal preparation, safety procedures, and instructions in use of assistive technology devices/adaptive equipment direct one-on-one contact, each 15 minutes)

- 97750 (Physical performance test or measurement (eg, musculoskeletal, functional capacity), with written report, each 15 minutes)

- 97755 (Assistive technology assessment (e.g., to restore, augment or compensate for existing function, optimize functional tasks and/or maximize environmental accessibility), direct one-on-one contact, with written report, each 15 minutes)

- 97760 (Orthotic(s) management and training (including assessment and fitting when not otherwise reported), upper extremity(ies), lower extremity(ies) and/or trunk, initial orthotic(s) encounter, each 15 minutes)

- 97761 (Prosthetic(s) training, upper and/or lower extremity(ies), initial prosthetic(s) encounter, each 15 minutes)

- 92521 (Evaluation of speech fluency (eg, stuttering, cluttering))

- 92522 (Evaluation of speech sound production (eg, articulation, phonological process, apraxia, dysarthria))

- 92523 (Evaluation of speech sound production (eg, articulation, phonological process, apraxia, dysarthria); with evaluation of language comprehension and expression (eg, receptive and expressive language))

- 92524 (Behavioral and qualitative analysis of voice and resonance)

- 92507 (Treatment of speech, language, voice, communication, and/or auditory processing disorder; individual)

## 17. Radiation Treatment Management Services

The code used to report radiation treatment management services includes several components, including reviewing the radiation dose and various treatment parameters, as well as weekly face-to-face visits with the patient to assess the patient's response to treatment and manage any symptoms the patient may be experiencing. We believe that in the context of the PHE for the COVID-19 pandemic, the weekly face-to-face visit component of this service could be conducted via telehealth when the billing practitioner weighs the exposure risks against the value of in-person assessment on a case-by-case basis. Therefore, we are adding CPT code 77427 (Radiation treatment management, 5 treatments) to the telehealth list so that the required face-to-face visit can be furnished via telehealth.

We believe that allowing the services listed above to be furnished as Medicare telehealth services will significantly increase the ability of Medicare physicians and practitioners to work without increasing exposure risk to themselves, their patients, and the broader community. Given widespread concerns regarding the health and safety

of our beneficiaries and health care providers during the PHE for the COVID–19 pandemic, we seek input on whether there are other services where the use of telecommunications technology could mitigate the exposure risk, and where there is clear clinical benefit to using such technology in furnishing the service.

We note that the inclusion of this code on the telehealth list to ensure that the included visits can be furnished via telehealth is similar to the inclusion of the transitional care management codes on the telehealth list. In both of these cases, the non-face-to-face portions of the service are not considered telehealth services that are subject to any of the payment provisions specific to telehealth services under section 1834(m) of the Act.

- CPT code 77427 (*Radiation treatment management, 5 treatments*)

As we noted above, we have previously considered adding many of these services to the Medicare telehealth list in prior rulemaking and declined, in many cases citing concerns over patient acuity and the feasibility of fulfilling all of the required elements of a service via communication technology. However, in the context of the PHE for the COVID–19 pandemic with specific regard to the exposure risks noted above, we recognize the clinical benefit of access to medically reasonable and necessary services furnished using telecommunications technology as opposed to the potential lack of access that could occur to mitigate the risk of disease exposure. We are also interested in learning of any potential negative consequences of adding these CPT codes to the list of telehealth services on an interim basis.

#### *B. Frequency Limitations on Subsequent Care Services in Inpatient and Nursing Facility Settings, and Critical Care Consultations and Required “Hands-On” Visits for ESRD Monthly Capitation Payments*

In adding some services to the Medicare telehealth list, we have done so while including certain restrictions on how frequently a service may be furnished via Medicare telehealth to ensure that the services met the category 1 or 2 criteria. For example, in the CY 2011 PFS final rule (75 FR 73317 through 73318), we added the subsequent hospital care services to the Medicare telehealth list. We stated that, because of our concerns regarding the potential acuity of hospital inpatients, we would limit the provision of subsequent hospital care services through telehealth to once every 3 days. Similarly, when we added subsequent

nursing facility visits to the Medicare telehealth list, we stated our concerns regarding the potential acuity and complexity of nursing facility (NF) patients, we would limit the provision of subsequent nursing facility care services furnished through telehealth to once every 30 days.

Given our assessment that under the PHE for the COVID–19 pandemic, there is a patient population that would otherwise not have access to clinically appropriate in-person treatment, we do not believe these frequency limitations are appropriate or necessary. In our prior analysis, for example, we were concerned that patients might not receive the necessary in-person services for nursing facility or hospital inpatient services. Since in the context of this PHE, telehealth visits mitigate exposure risk, fewer in-person visits may reflect the most appropriate care, depending on the needs of individual patients. Consequently, on an interim basis, we are removing the frequency restrictions for each of the following listed codes for subsequent inpatient visits and subsequent NF visits furnished via Medicare telehealth for the duration of the PHE for the COVID–19 pandemic. Similarly, we note that we previously limited critical care consultations through telehealth to only once per day, given the patient acuity involved in critical care. However, we also understand that critical care patients have significant exposure risks such that more frequent services furnished via telehealth may reflect the best available care in the context and for the duration of the PHE for the COVID–19 pandemic. For this reason, we are also removing the restriction that critical care consultation codes may only be furnished to a Medicare beneficiary once per day. These restrictions were established through rulemaking and implemented through systems edits.

#### 1. Subsequent Inpatient Visits: CPT Codes

- 99231 (*Subsequent hospital care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: A problem focused interval history; A problem focused examination; Medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is stable, recovering or improving. Typically, 15 minutes are spent at the bedside and on the patient's hospital floor or unit.*)

*bedside and on the patient's hospital floor or unit.)*

- 99232 (*Subsequent hospital care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: An expanded problem focused interval history; An expanded problem focused examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is responding inadequately to therapy or has developed a minor complication. Typically, 25 minutes are spent at the bedside and on the patient's hospital floor or unit.)*

- 99233 (*Subsequent hospital care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: A detailed interval history; A detailed examination; Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is unstable or has developed a significant complication or a significant new problem. Typically, 35 minutes are spent at the bedside and on the patient's hospital floor or unit.)*

#### 2. Subsequent Nursing Facility Visits: CPT Codes

- 99307 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: A problem focused interval history; A problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is stable, recovering, or improving. Typically, 10 minutes are spent at the bedside and on the patient's facility floor or unit.)*

- 99308 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: An expanded problem focused interval history; An expanded problem focused examination; Medical decision making of low complexity.*)

*Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is responding inadequately to therapy or has developed a minor complication. Typically, 15 minutes are spent at the bedside and on the patient's facility floor or unit.)*

- 99309 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: A detailed interval history; A detailed examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient has developed a significant complication or a significant new problem. Typically, 25 minutes are spent at the bedside and on the patient's facility floor or unit.)*

- 99310 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: A comprehensive interval history; A comprehensive examination; Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. The patient may be unstable or may have developed a significant new problem requiring immediate physician attention. Typically, 35 minutes are spent at the bedside and on the patient's facility floor or unit.)*

### 3. Critical Care Consultation Services: HCPCS Codes

- G0508 (*Telehealth consultation, critical care, initial, physicians typically spend 60 minutes communicating with the patient and providers via telehealth.)*

- G0509 (*Telehealth consultation, critical care, subsequent, physicians typically spend 50 minutes communicating with the patient and providers via telehealth.)*

We are seeking information on how these services are furnished via telecommunications technology to ensure that patients are safe and receiving adequate care.

### 4. Required "Hands-On" Visits for ESRD Monthly Capitation Payments

In the "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005" final rule with comment period (69 FR 66236, November 15, 2004) (hereinafter referred to as the CY 2005 PFS final rule with comment period), we added ESRD related services to the Medicare telehealth list; however, we specified that the required clinical examination of the vascular access site must be furnished face-to-face "hands on" (without the use of an interactive telecommunications system) by physician, clinical nurse specialist (CNS), nurse practitioner (NP), or physician assistant (PA) (69 FR 66278). On an interim basis in light of the PHE for the COVID-19 pandemic, we are instead permitting the required clinical examination to be furnished as a Medicare telehealth service during the PHE for the COVID-19 pandemic. We note that sections 1881(b)(3) and 1834(m) of the Act allow an individual determined to have ESRD receiving home dialysis to choose to receive certain monthly ESRD-related clinical assessments via telehealth on or after January 1, 2019. The Bipartisan Budget Act of 2018 (Pub. L. 115–123, enacted on February 9, 2018) (BBA of 2018) amended section 1881(b)(3)(B) of the Act to require that such an individual must receive a face-to-face visit, without the use of telehealth, at least monthly in the case of the initial 3 months of home dialysis and at least once every 3 consecutive months after the initial 3 months. Due to the conditions presented by the PHE, we are also exercising enforcement discretion on an interim basis to relax enforcement in connection with the requirements under section 1881(b)(3)(B) of the Act that certain visits be furnished without the use of telehealth for services furnished during the PHE. Specifically, CMS will not conduct review to consider whether those visits were conducted face-to-face, without the use of telehealth. The following CPT codes, when furnished via Medicare telehealth, are impacted by these policies:

- 90951 (*End-stage renal disease (ESRD) related services monthly, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 4 or more face-to-face visits by a physician or other qualified health care professional per month)*

- 90952 (*End-stage renal disease (ESRD) related services monthly, for patients younger than 2 years of age to*

*include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 2–3 face-to-face visits by a physician or other qualified health care professional per month)*

- 90953 (*End-stage renal disease (ESRD) related services monthly, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 1 face-to-face visit by a physician or other qualified health care professional per month)*

- 90954 (*End-stage renal disease (ESRD) related services monthly, for patients 2–11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 4 or more face-to-face visits by a physician or other qualified health care professional per month)*

- 90955 (*End-stage renal disease (ESRD) related services monthly, for patients 2–11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 2–3 face-to-face visits by a physician or other qualified health care professional per month)*

- 90957 (*End-stage renal disease (ESRD) related services monthly, for patients 12–19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 4 or more face-to-face visits by a physician or other qualified health care professional per month)*

- 90958 (*End-stage renal disease (ESRD) related services monthly, for patients 12–19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 2–3 face-to-face visits by a physician or other qualified health care professional per month)*

- 90959 (*End-stage renal disease (ESRD) related services monthly, for patients 12–19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 1 face-to-face visit by a physician or other qualified health care professional per month)*

- 90960 (*End-stage renal disease (ESRD) related services monthly, for patients 20 years of age and older; with 4 or more face-to-face visits by a physician or other qualified health care professional per month)*

- 90961 (*End-stage renal disease (ESRD) related services monthly, for patients 20 years of age and older; with*

*2–3 face-to-face visits by a physician or other qualified health care professional per month)*

- 90962 (*End-stage renal disease (ESRD) related services monthly, for patients 20 years of age and older; with 1 face-to-face visit by a physician or other qualified health care professional per month*)

- 90963 (*End-stage renal disease (ESRD) related services for home dialysis per full month, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents*)

- 90964 (*End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 2–11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents*)

- 90965 (*End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 12–19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents*)

- 90966 (*End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 20 years of age and older*)

- 90967 (*End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients younger than 2 years of age*)

- 90968 (*End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 2–11 years of age*)

- 90969 (*End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 12–19 years of age*)

- 90970 (*End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 20 years of age and older*)

#### C. Telehealth Modalities and Cost-Sharing

##### 1. Clarifying Telehealth Technology Requirements

Our regulation at § 410.78(a)(3) states that telephones, facsimile machines, and electronic mail systems do not meet the definition of an interactive telecommunications systems for purposes of Medicare telehealth services. As we interpret it, this regulation does not apply to mobile computing devices that include audio and video real-time interactive capabilities, even though such devices are now referred to colloquially as

“phones” since they can also be used for audio-only telecommunications. In light of the PHE for the COVID–19 pandemic, we believe it is important to avoid the potential perception that this language might prohibit use of any device that could otherwise meet the interactive requirements for Medicare telehealth, especially given that leveraging use of such readily available technology may be of critical importance.

Therefore, we are revising § 410.78(a)(3) to add an exception to this language on an interim basis for the duration of the PHE for the COVID–19 pandemic providing that for the duration of the public health emergency as defined in § 400.200, “interactive telecommunications system” means multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner.

In addition, the HHS Office for Civil Rights (OCR) is exercising enforcement discretion and waiving penalties for HIPAA<sup>4</sup> violations against health care providers that serve patients in good faith through everyday communications technologies, such as FaceTime or Skype, during the PHE for the COVID–19 pandemic. For more information, see <https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/index.html>. While OCR is not imposing penalties for noncompliance with the regulatory requirements under HIPAA against covered providers in connection with the good faith provision of telehealth during the PHE for the COVID–19 pandemic, HHS, OIG, and DOJ continue to actively monitor for any healthcare fraud and abuse, including potential Medicare coronavirus scams.

##### 2. Beneficiary Cost-Sharing

In response to the unique circumstances resulting from the outbreak of COVID–19 and the Secretary’s January 31, 2020 determination under section 319 of the Public Health Service Act that a PHE exists and has existed since January 27, 2020 (COVID–19 Declaration), the Office of Inspector General (OIG) issued a Policy Statement<sup>5</sup> to notify physicians and other practitioners that they will not be subject to administrative sanctions for reducing or waiving any cost-sharing obligations Federal health

care program beneficiaries may owe for telehealth services furnished consistent with the then applicable coverage and payment rules. OIG’s Policy Statement is not limited to the services governed by § 410.78 but applies to a broad category of non-face-to-face services furnished through various modalities, including telehealth visits, virtual check-in services, e-visits, monthly remote care management, and monthly remote patient monitoring. The Policy Statement applies to a physician or other practitioner billing for services provided remotely through information or communication technology or a hospital or other eligible individual or entity billing on behalf of the physician or practitioner for such services when the physician or other practitioner has reassigned his or her right to receive payments to such individual or entity.

#### D. Communication Technology-Based Services (CTBS)

In the “Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; Medicaid Promoting Interoperability Program; Quality Payment Program-Extreme and Uncontrollable Circumstance Policy for the 2019 MIPS Payment Year; Provisions From the Medicare Shared Savings Program-Accountable Care Organizations-Pathways to Success; and Expanding the Use of Telehealth Services for the Treatment of Opioid Use Disorder Under the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act” final rule (83 FR 59452 through 60303) (hereinafter referred to as the CY 2019 PFS final rule), we noted that under current PFS payment rules, Medicare routinely pays for many kinds of services that are furnished via telecommunications technology (83 FR 59482), but are not considered Medicare telehealth services. These communication technology-based services (CTBS) include, for example, certain kinds of remote patient monitoring (either as separate services or as parts of bundled services), and interpretations of diagnostic tests when furnished remotely. These services are different than the kinds of services specified in section 1834(m) of the Act, in that they are not the kind of services that are ordinarily furnished in person but are routinely furnished using a telecommunications system.

In the CY 2019 PFS final rule, we finalized separate payment for a number

<sup>4</sup> Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191, enacted August 21, 1996).

<sup>5</sup> <https://oig.hhs.gov/fraud/docs/alertsandbulletins/2020/policy-telehealth-2020.pdf>.

of services that could be furnished via telecommunications technology, but that are not Medicare telehealth services. Specifically, we finalized Healthcare Common Procedure Coding System (HCPCS) code G2010 (*Remote evaluation of recorded video and/or images submitted by an established patient (e.g., store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment)*), and HCPCS code G2012 (*Brief communication technology-based service, e.g. virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion*). We finalized these codes as part of the set of codes that is only reportable by the physicians and practitioners who can furnish evaluation and management (E/M) services. We stated that we believed this was appropriate since the service describes a check-in directly with the billing practitioner to assess whether an office visit is needed. However, we did note that similar check-ins provided by nurses and other clinical staff can be important aspects of coordinated patient care (83 FR 59486).

We also finalized that these services be limited to established patients, and that beneficiary consent must be documented in the patient's medical record for each service (83 FR 59487). This latter provision was amended in the CY PFS 2020 final rule to allow for a single beneficiary consent to be obtained annually (84 FR 62699). These requirements also apply to monthly care management and remote patient monitoring services.

In the context of the PHE for the COVID–19 pandemic, when brief communications with practitioners and other non-face-to-face services might mitigate the need for an in-person visit that could represent an exposure risk for vulnerable patients, we believe that these services should be available to as large a population of Medicare beneficiaries as possible. In some cases, use of telecommunication technology could mitigate the exposure risk, and in such cases, the clinical benefit of using technology to furnish the service is self-apparent. This would be especially true

should a significant increase in the number of people or health care professionals needing treatment or isolation occur in a way that would limit access to brief communications with established providers. Therefore, on an interim basis, during the PHE for the COVID–19 pandemic, we are finalizing that these services, which may only be reported if they do not result in a visit, including a telehealth visit, can be furnished to both new and established patients. We are also making clear that the consent to receive these services can be documented by auxiliary staff under general supervision. While we continue to believe that beneficiary consent is necessary so that the beneficiary is notified of any applicable cost sharing, we do not believe that the timing or manner in which beneficiary consent is acquired should interfere with the provision of one of these services. Therefore, we are finalizing on an interim basis during the PHE for the COVID–19 pandemic that, while consent to receive these services must be obtained annually, it may be obtained at the same time that a service is furnished. We are also re-emphasizing that this consent may be obtained by auxiliary staff under general supervision, as well as by the billing practitioner. We are retaining the requirement that in instances when the brief communication technology-based service originates from a related E/M service (including one furnished as a telehealth service) provided within the previous 7 days by the same physician or other qualified health care professional, that this service would be considered bundled into that previous E/M service and would not be separately billable.

In the “Medicare Program; CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations Final Rule” (84 FR 62568, November 15, 2019) (hereinafter referred to as the CY 2020 PFS final rule), we finalized separate payment for CPT codes 99421 (*Online digital evaluation and management service, for an established*

*patient, for up to 7 days, cumulative time during the 7 days; 5–10 minutes*), 99422 (*Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 11–20 minutes*), and 99423 (*Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 21 or more minutes*). We also finalized separate payment for HCPCS codes G2061 (*Qualified nonphysician healthcare professional online assessment and management, for an established patient, for up to seven days, cumulative time during the 7 days; 5–10 minutes*), G2062 (*Qualified nonphysician healthcare professional online assessment and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 11–20 minutes*), and G2063 (*Qualified nonphysician qualified healthcare professional assessment and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 21 or more minutes*) (84 FR 62796).

In the context of the PHE for the COVID–19 pandemic, where communications with practitioners might mitigate the need for an in-person visit that could represent an exposure risk for vulnerable patients, we do not believe the limitation of these services to established patients is warranted. While some of the code descriptors refer to “established patient,” during the PHE, we are exercising enforcement discretion on an interim basis to relax enforcement of this aspect of the code descriptors. Specifically, we will not conduct review to consider whether those services were furnished to established patients.

Additionally, in the CY 2020 PFS final rule (84 FR 62796), we stated that HCPCS codes G2061–G2063, specific to practitioners who do not report E/M codes, may describe services outside the scope of current Medicare benefit categories and as such, may not be eligible for Medicare payment. We have received a number of questions regarding which benefit categories HCPCS codes G2061–G2063 fall under. In response to these requests, we are clarifying here that there are several types of practitioners who could bill for these services. For example, the services described by these codes could be furnished as licensed clinical social worker services, clinical psychologist services, physical therapist services, occupational therapist services, or speech language pathologist services, so practitioners that report services in

those benefit categories could also report these online assessment and management services.

On an interim basis, during the PHE for the COVID–19 pandemic, we are also broadening the availability of HCPCS codes G2010 and G2012 that describe remote evaluation of patient images/video and virtual check-ins. We recognize that in the context of the PHE for the COVID–19 pandemic, practitioners such as licensed clinical social workers, clinical psychologists, physical therapists, occupational therapists, and speech-language pathologists might also utilize virtual check-ins and remote evaluations instead of other, in-person services within the relevant Medicare benefit to facilitate the best available appropriate care while mitigating exposure risks. We note that this is not an exhaustive list and we are seeking input on other kinds of practitioners who might be furnishing these kinds of services as part of the Medicare services they furnish in the context of the PHE for the COVID–19 pandemic.

Further, to facilitate billing of the CTBS services by therapists for the reasons described above, we are designating HCPCS codes G2010, G2012, G2061, G2062, or G2063 as CTBS “sometimes therapy” services that would require the private practice occupational therapist, physical therapist, and speech-language pathologist to include the corresponding GO, GP, or GN therapy modifier on claims for these services. CTBS therapy services include those furnished to a new or established patients that the occupational therapist, physical therapist, and speech-language pathologist practitioner is currently treating under a plan of care.

#### *E. Direct Supervision by Interactive Telecommunications Technology*

Many services paid under the PFS can be paid when provided under a level of physician or nonphysician practitioner (NPP) supervision rather than personal performance. In many cases, the supervision requirements in physician office settings necessitate the presence of the physician or NPP in a particular location, usually in the same location as the beneficiary when the service is provided. For example, as described at § 410.26, services incident to a physicians’ service usually require the direct supervision of a physician. As currently defined in § 410.32(b)(3)(ii), direct supervision means that the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the

procedure. It does not mean that the physician must be present in the room when the procedure is performed.

Given the circumstances of the PHE for the COVID–19 pandemic, we recognize that in some cases, the physical proximity of the physician or practitioner might present additional exposure risks, especially for high risk patients isolated for their own protection or cases where the practitioner has been exposed to the virus but could otherwise safely supervise from another location using telecommunications technology. In these cases, we believe that the current requirement would necessarily limit access to procedures and tests that could be appropriately supervised by a physician isolated for purposes of limiting exposure to COVID–19. For example, we consider the possibility that patients routinely receiving medically necessary physician-administered drugs at the office of a physician may lose access to the provision of that drug should the physician who regularly supervises the provision of that drug be isolated for purposes of minimizing exposure risks. Likewise, should that same patient need to be isolated for purposes of exposure risk based on presumed or confirmed COVID–19 infection, administering such a drug in the patient’s home would require the billing professional to accompany the clinical staff to the patient’s home, presumably with the necessary personal protective equipment (PPE) available to both the physician and the clinical staff.

In some cases, depending upon the unique circumstances of individual patients and billing physicians, we believe that telecommunications technology could be used in a manner that would facilitate the physician’s immediate availability to furnish assistance and direction without necessarily requiring the physician’s physical presence in the location where the service is being furnished, such as the office suite or the patient’s home. For example, we believe that use of real-time, audio and video telecommunications technology allows for a billing practitioner to observe the patient interacting with or responding to the in-person clinical staff through virtual means, and thus, their availability to furnish assistance and direction could be met without requiring the physician’s physical presence in that location. We note that to be covered under Part B, drugs furnished “incident to” are typically injectable drugs that are bought by the physician, in ordinary circumstances are administered in the physician’s

office, and then billed by the physician to the Medicare Administrative Contractor (MAC). By definition, “incident to a physician’s professional service” requires the item or service to be billed by the physician. We also note that the supervision requirements that apply to both services incident to a physicians’ service and diagnostic tests do not necessarily reflect the appropriate level of supervision for particular patients, services, and health care workers. Instead, we view these levels as the minimum possible requirement for provision of the service for purposes of Medicare payment. Likewise, even in the context of the PHE for the COVID–19 pandemic and the inherent exposure risks for Medicare beneficiaries, physicians and other health care providers, we believe that in many cases furnishing services without the physical presence of the physician in the same location would not be appropriate. However, we recognize that in some cases, technology would allow appropriate supervision without the physical presence of a physician. In the context of the PHE for the COVID–19 pandemic, given the risks of exposure, the immediate potential risk to needed medical care, the increased demand for health care professionals in the context of the PHE for the COVID–19 pandemic, and the widespread use of telecommunications technology, we believe that individual practitioners are in the best position to make decisions based on their clinical judgement in particular circumstances. Consequently, we are revising the definition of direct supervision to allow, for the duration of the PHE for the COVID–19 pandemic, direct supervision to be provided using real-time interactive audio and video technology. We are seeking information from commenters as to whether there should be any guardrails and what kind of risk might this policy introduce for beneficiaries while reducing risk of COVID–19 spread. We note that this change is limited to only the manner in which the supervision requirement can be met, and does not change the underlying payment or coverage policies related to the scope of Medicare benefits, including Part B drugs. We also note that any and all applicable rules regarding safe transportation and proper waste disposal continue to apply.

We note that in specifying that direct supervision includes virtual presence through audio/video real-time communications technology during the PHE for the COVID–19 pandemic, this can include instances where the physician enters into a contractual arrangement for auxiliary personnel as

defined in § 410.26(a)(1), to leverage additional staff and technology necessary to provide care that would ordinarily be provided incident to a physicians' service (including services that are allowed to be performed via telehealth). For example, physicians may enter into contractual arrangements with a home health agency (defined under section 1861(o) of the Act), a qualified infusion therapy supplier (defined under section 1861(iii)(3)(D) of the Act), or entities that furnish ambulance services in order to utilize their nurses or other clinical staff as auxiliary personnel under leased employment (§ 410.26(a)(5)). In such instances, the provider/supplier would seek payment for any services they provided from the billing practitioner and would not submit claims to Medicare for such services. For telehealth services that need to be personally provided by a physician, such as an E/M visit, the physician would need to personally perform the E/M visit and report that service as a Medicare telehealth service. However, we acknowledge that there may be instances where the physician may want to use auxiliary personnel to be present in the home with the patient during the telehealth service, though this is not required for telehealth services under section 1834(m) of the Act. Other services, including both face-to-face and non-face-to-face services, could be provided incident to a physicians' service by a nurse or other auxiliary personnel, as long as the billing practitioner is providing appropriate supervision through audio/video real-time communications technology (or in person), when needed. We would not expect that services furnished at a patient's home incident to a physician service would usually occur during the same period as a home health episode of care, and we will be monitoring claims to ensure that services are not being inappropriately unbundled from payments under the home health PPS.

For the reasons discussed above, on an interim basis for the duration of the PHE for the COVID-19 pandemic, we are altering the definition of direct supervision at § 410.32(b)(3)(ii), to state that necessary presence of the physician for direct supervision includes virtual presence through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider. We are revising § 410.32(b)(3)(ii) to include, during a PHE, as defined in § 400.200 of this chapter, the presence of the physician includes virtual presence through

audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider.

#### 1. Supervision Changes for Certain Hospital and CAH Diagnostic and Therapeutic Services

For all of the same reasons described above, we are adopting similar changes in the regulations at § 410.28(e)(1) with respect to the supervision of diagnostic services furnished directly or under arrangement in the hospital or in an on-campus or off-campus outpatient department of the hospital, as defined in § 413.65. We note that under current Medicare rules, most therapeutic services in the hospital require only general supervision and the supervision requirements for diagnostic services generally conform to the service-level supervision levels required for payment under the PFS. Because we have every reason to believe that potential exposure risks and limits on the availability of medical professionals could equally apply to hospital services, we are amending the definition of direct supervision for hospital services for the duration of the PHE for the COVID-19 pandemic so it continues to conform with the applicable definitions for services paid under the PFS. As stated above, we believe this change is necessary due to the circumstances of the PHE for the COVID-19 pandemic. Specifically, we recognize that in some cases, the physical proximity of the physician or practitioner might present additional exposure risks, especially for high risk patients isolated for their own protection or cases where the practitioner has been exposed to the virus but could otherwise safely supervise from another location using telecommunications technology. In these cases, we believe that the current definition would necessarily limit access to diagnostic procedures and tests that could be appropriately supervised by a physician, including one who is isolated for purposes of limiting exposure to COVID-19.

In addition, with respect to pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services described in the regulations at §§ 410.47 and 410.49, respectively, we are adopting a similar change under § 410.27(a)(1)(iv)(D), for the duration of the PHE for the COVID-19 pandemic, for all the reasons described above, to specify that direct supervision for these services includes virtual presence through audio/video real-time communications technology when use of such technology is

indicated to reduce exposure risks for the beneficiary or health care provider.

#### *F. Clarification of Homebound Status Under the Medicare Home Health Benefit*

Sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act state that payment for home health services is made when a physician certifies that such services are or were required because the individual is or was confined to his home and needs or needed skilled nursing care (other than solely venipuncture for the purpose of obtaining a blood sample) on an intermittent basis or physical or speech therapy or, in the case of an individual who has been furnished home health services based on such a need and who no longer has such a need for such care or therapy, continues or continued to need occupational therapy. In addition, the physician must certify that a plan for furnishing such services to such individual has been established and is periodically reviewed by the physician and that such services are or were furnished while the individual was under the care of a physician. Also, in the case of a certification made by a physician after January 1, 2010, prior to making such certification the physician must document that the physician himself or herself, or an NP or clinical nurse specialist (CNS) (as those terms are defined in section 1861(aa)(5) of the Act) who is working in collaboration with the physician in accordance with State law, or a certified nurse-midwife (as defined in section 1861(gg) of the Act) as authorized by State law, or a PA (as defined in section 1861(aa)(5) of the Act) under the supervision of the physician, has had a face-to-face encounter (including through use of telehealth, subject to the requirements in section 1834(m) of the Act, and other than for encounters that are incident to services involved, as described in section II.E. of this IFC) with the individual within a reasonable timeframe as determined by the Secretary.

Most recently, we have been asked by stakeholders to provide more clarity on whether patients who are instructed to remain in their homes or are under "self-quarantine" are considered "confined to the home" or "homebound" for purposes of the Medicare home health benefit in the context of the PHE for the COVID-19 pandemic. Per sections 1814(a) and 1835(a) of the Act, an individual shall be considered to be "confined to his home" if the individual has a condition, due to an illness or injury, that restricts the ability of the individual to leave his

or her home except with the assistance of another individual or the aid of a supportive device (such as crutches, a cane, a wheelchair, or a walker), or if the individual has a condition such that leaving his or her home is medically contraindicated. While an individual does not have to be bedridden to be considered “confined to his home”, the condition of the individual should be such that there exists a normal inability to leave home and, that leaving home requires a considerable and taxing effort by the individual.

The definition of “confined to the home” (that is, “homebound”) allows patients to be considered “homebound” if it is medically contraindicated for the patient to leave the home. As an example for the PHE for COVID–19 pandemic, this would apply for those patients: (1) Where a physician has determined that it is medically contraindicated for a beneficiary to leave the home because he or she has a confirmed or suspected diagnosis of COVID–19; or (2) where a physician has determined that it is medically contraindicated for a beneficiary to leave the home because the patient has a condition that may make the patient more susceptible to contracting COVID–19. A patient who is exercising “self-quarantine” for one’s own safety would not be considered “confined to the home” unless a physician certifies that it is medically contraindicated for the patient to leave the home. For the PHE for the COVID–19 pandemic, the CDC is currently advising that older adults and individuals with serious underlying health conditions stay home (CDC’s guidance is interim and is expected to continue to be updated as warranted).<sup>6</sup> As such, we expect that many Medicare beneficiaries could be considered “confined to the home”. However, determinations of whether home health services are reasonable and necessary, including whether the patient is homebound and needs skilled services, must be based on an assessment of each beneficiary’s individual condition and care needs.

In cases where it is medically contraindicated for the patient to leave the home, the medical record documentation for the patient must include information as to why the individual condition of the patient is such that leaving the home is medically contraindicated. With regards to a pandemic outbreak of an infectious disease, this can include reviewing and applying any guidance on risk assessment and public health

management issued by the CDC. For example, the CDC interim guidance “Preventing the Spread of Coronavirus Disease 2019 in Homes and Residential Communities” applies for both confirmed or suspected COVID–19 states that patients who are medically stable enough to receive care in the home must isolate at home during their illness.<sup>7</sup> Additionally, these guidelines state that patients should restrict activities outside the home, except for getting medical care. These restrictions include that the individual not go to work, school, or public areas, as well as avoiding use of public transportation, ride-sharing, or taxis; making it such that there exists a normal inability for an individual to leave home and leaving home would require a considerable and taxing effort.

In regards to those circumstances in which the patient does not have confirmed or suspected diagnosis of an infectious disease, such as COVID–19, but the patient’s physician states that it is medically contraindicated for the patient to leave the home because the patient’s condition may make the patient more susceptible to contracting a pandemic disease, the patient would be considered “confined to the home” or “homebound” for purposes of this eligibility requirement. For example, if a patient is having an exacerbation of chronic obstructive pulmonary disease (COPD) and the physician certifies that it is medically contraindicated to leave the home because the patient’s compromised respiratory system makes him or her more likely to contract an infectious disease, such as COVID–19, the patient would be considered “confined to the home” in alignment with Medicare home health eligibility criteria. Another example of this type of scenario would be a cancer patient receiving chemotherapy treatment and where the physician states that it is medically contraindicated for the patient to leave the home because the patient may be more at risk of contracting an infectious disease because of the patient’s immunocompromised state. In both examples, the medical contraindication makes it such that there exists a normal inability for an individual to leave home and leaving home safely would require a considerable and taxing effort.

In addition to being considered “confined to the home” or “homebound”, the patient must meet the other Medicare home health eligibility requirements to receive Medicare home health services. That is,

the beneficiary must be under the care of a physician; receiving services under a plan of care established and periodically reviewed by a physician; be in need of skilled nursing care on an intermittent basis or physical therapy or speech-language pathology; or have a continuing need for occupational therapy. Even if the patient is confined to the home because of a suspected diagnosis of an infectious disease as part of a pandemic event, a home health visit solely to obtain a nasal or throat culture would not be considered a skilled service because it would not require the skills of a nurse to obtain the culture as the specimen could be obtained by an appropriately-trained medical assistant or laboratory technician. However, a home health nurse, during an otherwise covered skilled visit, could obtain the nasal or throat culture to send to the laboratory for testing. Please see section II.M. of this IFC for further discussion about how a Medicare patient without a skilled need who is under self-quarantine may be tested at home.

We believe this clarification is not limited to the PHE for the COVID–19 pandemic, but would also apply for other outbreaks of an infectious disease and instances where the condition of a patient is such that it is medically contraindicated for the patient to leave his or her home. We solicit comments on this clarification.

#### *G. The Use of Technology Under the Medicare Home Health Benefit During the PHE for the COVID–19 Pandemic*

Section 1895 of the Act outlines the statutory parameters of the home health prospective payment system (HH PPS) that was implemented on October 1, 2000. The HH PPS provides payment for all services furnished under the Medicare home health benefit as outlined in section 1861(m) of the Act in the form of a “bundled” 30-day unit of payment that is adjusted for case-mix and area wage differences in accordance with section 1895(b) of the Act. Section 1895(e)(1)(A) of the Act states that nothing under section 1895 of the Act prevents a home health agency (HHA) from furnishing services via a telecommunications system, as long as such services do not: (1) Substitute for in-person home health services ordered as part of a plan of care certified by a physician; and (2) are not considered a home health visit for purposes of eligibility or payment. In the CY 2019 HH PPS proposed rule (83 FR 32425), we stated that “remote patient monitoring” is one type of service that can be furnished via a telecommunications system to augment a home health plan of care without

<sup>6</sup> <https://www.cdc.gov/coronavirus/2019-ncov-specific-groups/high-risk-complications.html>.

<sup>7</sup> <https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-prevent-spread.html>.

substituting for an in-person visit. In the CY 2019 HH PPS final rule with comment (83 FR 56527), for purposes of the Medicare home health benefit, we finalized the definition of “remote patient monitoring” in regulation at 42 CFR 409.46(e) as the collection of physiologic data (for example, ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the HHA. We also included in regulation at § 409.46(e) that the costs of remote patient monitoring are considered allowable administrative costs (operating expenses) if remote patient monitoring is used by the HHA to augment the care planning process (83 FR 56527).

We received positive feedback from the policy changes finalized in the CY 2019 HH PPS final rule with comment period. Commenters encouraged us to even go further in adopting and promoting technology use in home health. Recently, we have been asked by stakeholders to provide more clarity on how HHAs can leverage technology to keep home health clinicians and patients safe during outbreaks of an infectious disease, such as the PHE for the COVID–19 pandemic. While we remain statutorily-prohibited from paying for home health services furnished via a telecommunications system if such services substitute for in-person home health services ordered as part of a plan of care and for paying directly for such services under the home health benefit, for the duration of the PHE for the COVID–19 pandemic, we are amending the regulations at § 409.43(a) on an interim basis to provide HHAs with the flexibility, in addition to remote patient monitoring, to use various types of telecommunications systems (that is, technology) in conjunction with the provision of in-person visits.

Specifically, we are amending the regulations at § 409.43(a) on an interim basis to state that the use of technology must be related to the skilled services being furnished by the nurse/therapist/therapy assistant to optimize the services furnished during the home visit or when there is a home visit. We are also amending the regulations at § 409.43(a) on an interim basis to state that the use of technology must be included on the home health plan of care along with a description of how the use of such technology will help to achieve the goals outlined on the plan of care without substituting for an in-person visit as ordered on the plan of care. As a reminder, the plan of care must be signed prior to submitting a

final claim to Medicare for payment (§ 409.43(c)(2)); therefore, HHAs have flexibility on the timing in which they obtain physician signatures for changes to the plan of care when incorporating the use of technology into the patient’s plan of care. In addition, HHAs may also provide services based on verbal orders in accordance with the regulations at §§ 484.60(b) and 409.43(d). Finally, on an interim basis HHAs can report the costs of telecommunications technology as allowable administrative and general (A&G) costs by identifying the costs using a subscript between line 5.01 through line 5.19.

We reiterate that by law the use of technology may not substitute for an in-person home visit ordered as part of the plan of care and services furnished via a telecommunications system cannot be considered a home health visit for purposes of eligibility or payment. However, we acknowledge that the use of such technology may result in changes to the frequency or types of visits outlined on the plan of care, especially to combat the PHE for the COVID–19 pandemic. For example, a patient recently discharged from the hospital after coronary bypass surgery was receiving home health skilled nursing visits three times a week for medication management, teaching and assessment. The patient developed a fever, cough, sore throat and moderate shortness of breath and now has a confirmed COVID–19 diagnosis, which the doctor has determined can be safely managed at home with home health services. The patient has been prescribed new medications for symptom management and oxygen therapy to support the patient’s respiratory status. The patient’s home health plan of care was updated to include an in-person skilled nursing visit once a week to assess the patient and to monitor for worsening symptoms. The plan of care was updated also to include a video consultation twice a week between the skilled nurse and the patient for medication management, teaching and assessment, as well as to obtain oxygen saturation readings that the patient relays to the nurse during the consultation.

With regards to payment under the HH PPS, if the primary reason for home health care is to provide care to manage the symptoms resulting from COVID–19, this 30-day period of care would be grouped into the Medication, Management, Teaching and Assessment (MMTA)—Respiratory clinical group, and it would be an early 30-day period of care with an institutional admission

source. Assuming a medium functional impairment level with “low” comorbidities, the low-utilization payment adjustment (LUPA) threshold would be 4 visits. Regardless if the patient continued to receive the original 3 in-person skilled nursing visits per week (12 visits total in the 30-day period) rather than the once per-week in-person skilled nursing visits (4 visits total in the 30-day period) the HHA would still receive the full 30-day payment amount (rather than paying per visit if the total number of visits was below the LUPA threshold). In this example, the use of technology is not a substitute for the provision of in-person visits as ordered on the plan of care, as the plan of care was updated to reflect a change in the frequency of the in-person visits and to include “virtual visits” as part of the management of the home health patient.

As discussed previously in section II.E “Direct Supervision by Interactive Telecommunications Technology” in this IFC, there may be instances during the PHE for the COVID–19 pandemic where physicians can enter into a contractual arrangement, that meets the definition of auxiliary personnel at § 410.26, with another provider/supplier type. For example, physicians may enter into contractual arrangements with a HHA, a qualified infusion therapy supplier, or other entity to leverage auxiliary personnel under leased employment (§ 410.26(a)(5)), including nurses or other clinical staff, to provide virtual visits for patients in their homes. These virtual visits are considered provided incident to a physician’s service, as long as the billing practitioner is providing appropriate supervision through audio/video real-time communications technology, when needed. Payment for such services would be made to the billing practitioner who would then make the appropriate payment to the contracted entity (for example, the HHA). This payment would be made in accordance with the PFS and would not be considered a home health service under the Medicare home health benefit. This particular flexibility can enable more patients to receive services at home via telehealth for instances in which there are no in-person visits that would trigger payment under the Medicare HH PPS. As such, we would not expect that services furnished at a patient’s home incident to a physician service will usually occur during the same period as a home health episode of care, and we will be monitoring claims that practitioners are billing under arrangement to ensure appropriate

services are being billed by the practitioner and not being inappropriately unbundled from payments under the HH PPS.

The remainder of this section includes information on examples of technology that can be leveraged in providing care in the home setting, such as telemedicine, interactive clinician “consulting” and other patient-facing technologies; and provides a summary of the regulations text we are amending in this IFC.

In general, technology has become an integral part of medicine across the entire spectrum of healthcare. Telemedicine, in particular has the potential to play a large role in enhancing the delivery of healthcare in the home for Medicare beneficiaries, including the provision of information, education, and services provided via telecommunications systems. One of the biggest benefits of telemedicine, separate from its potential to minimize risk to clinicians and patients during an outbreak of an infectious disease, is to increase access to healthcare to geographically disadvantaged and medically underserved populations, providing an improved quality of care.<sup>8</sup> Telemedicine and remote monitoring can also be used to encourage patient involvement and autonomy, and to increase the tools available for the home health provider.

Recent CMS site visits with HHAs, as well as meetings with industry associations detailed the extent to which HHAs are researching and integrating technology into their care. These organizations provided examples of technology they have tested and/or are currently using, ranging from patient facing apps on cell phones to robotics. Additionally, they provided examples of patients with specific home health needs that they believe would benefit most from leveraging technology in home health care. They indicated a wide variety of uses for technology in home health including medication management and teaching, behavioral/crisis or social work counseling, post-transplant monitoring, dietary counseling, and even functional training through remote occupational or physical therapy. In particular, they highlighted certain diagnoses and conditions for which they are already utilizing telecommunications systems. For diagnoses/conditions such as COPD, congestive heart failure (CHF), sepsis, and wounds, technology can offer an efficient way of monitoring chronic

respiratory and cardiovascular diseases that represent an increasingly high burden on healthcare systems.<sup>9</sup> We referenced some of the benefits of remote patient monitoring of chronic diseases in the CY 2019 HH PPS proposed rule (83 FR 32425), including readmission prevention and improved patient involvement and accountability.

Certain HHAs and industry groups have implemented technology that goes beyond remote patient monitoring for the treatment of chronic diseases. One such HHA utilizes two-way, interactive “consulting” between the nurse furnishing the home visit and a specialty clinician at the agency. The nurse furnishing the home visit can use a tablet to visually connect the patient with the specialty clinician or advanced practice nurse at the agency to assess swelling, breathing, or to review and reconcile medications. These specialty clinicians are also beneficial in treating acute conditions, such as wounds, or monitoring for the prevention of sepsis. Wound, Ostomy, and Continence Nurses (WOCNs) are being utilized for their specialized skills as consultants for the nurse in the home. The nurse furnishing the home visit can use a tablet to connect visually with the WOCN at the agency to consult on the management of the wound. If necessary, the WOCN can contact the physician or surgeon to relay progress or request a change in treatment. Specialized software can even be utilized to assess the wound with precision and accuracy, including measuring surface area and depth, to improve consistency of care.<sup>10</sup> Additionally, incorporating technology into home health may be beneficial in attracting these specialty clinicians, such as cardiac nurses and WOCNs, to homecare, which promotes the provision of a more advanced level of care; a benefit that will become imperative if the home health patient population, as a whole, exhibits more characteristics of an acute care population. Allowing advanced practice clinicians to consult virtually with the RN in the home may minimize transportation and labor costs and potentially improve patient access to specialty care.

Telecommunications systems are also playing a valuable role in managing patients at risk for sepsis after a hospitalization. Sepsis continues to be a top diagnosis for hospital 30-day readmission rates amongst Medicare

patients.<sup>11</sup> Utilizing individualized software platforms to monitor appetite, mental changes, biometrics, etc., which alert care providers of any changes that may indicate a problem, can be helpful in treating the patient in the home prior to the patient requiring hospitalization. These patient-facing devices (tablets or apps) can be programmed to require the patient to perform a virtual daily “check-in” to monitor for potential issues. If the “check-in” goes beyond specified individualized parameters, an alert will signal the HHA to follow-up with the critical care team following the patient to accelerate treatment. The software can also be programmed to deliver specific care instructions and reminders regarding hygiene or medications. In addition to disease-specific monitoring, patient-facing technologies can also be integral in promoting patient involvement and compliance. Certain scheduling and communication platforms allow HHAs to interface with patients in more ways than in-person visits or telephone calls. Some devices can “talk” to the patient, even utilizing multiple languages. Others can provide medication reminders, daily health tips, and assist in arranging for community or caregiver support.

Overall, we have seen how technology can expand the reach of healthcare into the home, through consultation with specialized clinicians and critical care teams, as well as through the integration of devices designed to increase patient involvement and compliance. As outlined above, incorporating these various forms of technology, in addition to remote patient monitoring as defined under the home health benefit (§ 409.46(e)), can be appropriate in furnishing home health services when used in conjunction with the provision of in-person visits. In addition, technology can be used to minimize the risk of exposure to clinicians, patients, and the public during an outbreak of an infectious disease, such as the PHE for the COVID-19 pandemic. Although HHAs have the flexibility, in addition to remote patient monitoring, to use various types of technology, payment for home health services remains contingent on the furnishing of a visit. Therefore, the use of technology must be related to the skilled services being furnished by the nurse or therapist or therapy assistant to optimize the services furnished during the home visit or when there is a home visit. To be eligible for the home health benefit, beneficiaries must need intermittent

<sup>8</sup> Int J Environ Res Public Health. 2013 Dec; 10(12): 6472–6484. Published online 2013 Nov 28. doi: 10.3390/ijerph10126472.

<sup>9</sup> Breathe (Sheff). 2016 Dec; 12(4): 350–356. doi: 10.1183/20734735.014616.

<sup>10</sup> <https://parablehealth.com/post-acute-inpatient>.

<sup>11</sup> <https://www.hcup-us.ahrq.gov/reports/statbriefs/sb225-Inpatient-US-Stays-Trends.pdf>.

skilled nursing or therapy services and must be considered homebound. Covered home health services include skilled nursing, home health aide, physical therapy, speech-language pathology, occupational therapy, medical social services, and medical supplies, provided on a visiting basis in a place of residence such as the individual's home (section 1861(m) of the Act). A visit is defined at § 409.48(c) as an episode of personal contact with the beneficiary by staff of the HHA or others under arrangements with the HHA, for the purpose of providing a covered service. Generally, one visit may be covered each time an HHA employee or someone providing home health services under arrangement with the HHA enters the beneficiary's home and provides a covered service to a beneficiary.

To appropriately recognize the role of technology in furnishing services under the Medicare home health benefit, the use of such technology must be included on the plan of care. The inclusion of technology on the plan of care must continue to meet the requirements at § 484.60, and must be tied to the patient-specific needs as identified in the comprehensive assessment and the measurable outcomes that the HHA anticipates will occur as a result of implementing the plan of care. For example, if a physician orders an in-person skilled nursing visit once a week to assess the patient and to monitor for worsening symptoms and a video consultation twice a week between the skilled nurse and the patient for medication management, teaching and assessment, as well as to obtain oxygen saturation readings that the patient relays to the nurse during the consult; the plan of care could specify that the goal of the video consultation is to increase patient adherence with medication regimen and oxygen use with no worsening respiratory symptoms.

In summary, we are amending the plan of care requirements at § 409.43(a) on an interim basis, for the purposes of Medicare payment, to state that the plan of care must include any provision of remote patient monitoring or other services furnished via a telecommunications system, and that these services cannot substitute for a home visit ordered as part of the plan of care and cannot be considered a home visit for the purposes of patient eligibility or payment. The plan of care must include a description of how the use of such technology will help to achieve the goals outlined on the plan of care. We believe that this change will help to increase access to technologies,

such as telemedicine and remote patient monitoring, that enable the necessary flexibility for Medicare beneficiaries to be able to receive medically necessary services without jeopardizing their health or the health of those who are providing such services, while minimizing the overall risk to public health during the PHE for the COVID-19 pandemic. As we stated above, HHAs can report the costs of telecommunications technology as allowable A&G costs on an interim basis by identifying the costs using a subscript between line 5.01 through line 5.19. We invite feedback on our interim changes to the plan of care requirements at § 409.43(a).

#### *H. The Use of Telecommunications Technology Under the Medicare Hospice Benefit*

As outlined in section II.G. of this IFC, The Use of Technology Under the Medicare Home Health Benefit, technology has become an integral part of medicine across the entire spectrum of healthcare. Telemedicine, in particular has the potential to play a large role in enhancing the delivery of healthcare in the home, including the provision of information, education, and services provided via telecommunications systems. One of the benefits of telemedicine is its potential to minimize risk to clinicians and patients during an outbreak of an infectious disease, such as the PHE for the COVID-19 pandemic. Recently, we have been asked by stakeholders to provide more clarity on how hospices can leverage technology to keep clinicians and patients safe during the PHE for the COVID-19 pandemic.

For the duration of the PHE for the COVID-19 pandemic, we are amending the hospice regulations at 42 CFR 418.204 on an interim basis to specify that when a patient is receiving routine home care, hospices may provide services via a telecommunications system if it is feasible and appropriate to do so to ensure that Medicare patients can continue receiving services that are reasonable and necessary for the palliation and management of a patients' terminal illness and related conditions without jeopardizing the patients' health or the health of those who are providing such services during the PHE for the COVID-19 pandemic. To appropriately recognize the role of technology in furnishing services under the hospice benefit, the use of such technology must be included on the plan of care. The inclusion of technology on the plan of care must continue to meet the requirements at § 418.56, and must be tied to the

patient-specific needs as identified in the comprehensive assessment and the measurable outcomes that the hospice anticipates will occur as a result of implementing the plan of care. The following is an example of where it could be appropriate to furnish hospice services via a telecommunications system during the PHE for the COVID-19 pandemic:

A terminally ill 85-year-old male with heart failure has been receiving hospice services and recently developed a fever, sore throat and cough. The patient has been diagnosed with suspected COVID-19 and his hospice plan of care now includes medications for symptom management. He is mildly short of breath but does not require supportive oxygen therapy. The patient's wife is concerned about potential for worsening cardiac and respiratory symptoms as a result of the patient's risk for increased complications due to COVID-19. The hospice plan of care has been updated to include remote patient monitoring with a telecommunications system to assess the patient's daily weight and oxygen saturation levels. The plan of care identifies the measurable goal that the patient will maintain an oxygen level above 92 percent and the patient will not gain more than 2 pounds in a 24-hour period. The plan of care identifies interventions if either of these goals are not met. The remote patient monitoring allows for more expedited modifications to the plan of care in response to the patient's changing needs.

We believe that this clarification in the regulations at § 418.204 will help to increase access to technologies, such as telemedicine and remote patient monitoring, that enable the necessary flexibility for patients to be able to receive necessary services without jeopardizing their health or the health of those who are providing those services, while minimizing the overall risk to public health during the PHE for the COVID-19 pandemic. Hospices are paid a per diem payment amount based on the level of care for each day that a patient is under a hospice election (§ 418.302). There is no payment beyond the per diem amount for the use of technology in providing services under the hospice benefit. For the purposes of the hospice claim submission, only in-person visits (with the exception of social work telephone calls) should be reported on the claim. However, hospices can report the costs of telecommunications technology used to furnish services under the routine home care level of care during the PHE for the COVID-19 pandemic as "other patient care services" using Worksheet A, cost center line 46, or a subscript of line 46 through 46.19, cost center code 4600 through 4619, and identifying this cost center as "PHE for COVID-19". We invite feedback on our changes to the